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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,850	04/09/2004	Michael John Dunkley	0198.00	2666

21968 7590 09/21/2005

NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,850

Applicant(s)

DUNKLEY ET AL.

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>detailed action</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Niccolai US patent 6705,313 B2**

As to claims 1-31, Niccolai discloses in figures 1 and 2 a handheld aerosolization apparatus comprising a housing defining a chamber 17 having a plurality of air inlets 20 the chamber being sized to receive a receptacle 18 which contains an aerosolizable pharmaceutical formulation (“powder” col.1 lines 59-60); a shield 2 which covers at least one but not all of the air inlets (also recites claim 14 limitation “a shield which covers a portion of but not all of at least one of the air inlets” and claim 19 limitation “a shield extending around only a portion of transverse circumference of the housing, the shield covering at least one air inlets”), whereby the shield prevents blockage 21 of the at least one air inlet by a user grasping the apparatus; and an end section 8 associated with the housing, the end section sized and shaped to be received in a user’s mouth or nose (col.3 lines 45-47) so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation the has exited the receptacle., wherein the shield is a portion of the end section (col.2 lines 61-63); wherein the end section is removably connected (snap fitting) to the housing and wherein the end section may be removed from the housing to provide access to the chamber (col.2 lines 61-63); wherein the shield comprises at least two covering portions (fig.2 21),

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each covering portion covering at least one inlet; wherein there are two covering portions and wherein the two covering portions are diametrically opposed (**fig.2, fins are located at the two opposing ends**), wherein the at least two covering portions are separated by open portions (**fig.2 seems to depict fins 21 at the two opposing ends of the shield. Therefore space between the two fins are considered open portion that are not covered by the fins**); wherein the open portions provide direct access to at least one inlet (**open portion would inherently consider to allow direct air flow**), wherein the shield extends longitudinally along the apparatus (**see fig.2**), wherein the receptacle is a capsule and further comprising a puncturing mechanism **15** in the housing for creating one or more openings (**fig.2 19**) in the capsule, wherein the puncture member is adapted to puncture only one end ("**lower end**") of the capsule (**since the mechanism is provided only one side of the device, the mechanism is inherently bound to puncture only one end of the receptacle/capsule**); wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (**see fig.2**).


Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shumaya B. Ali
Examiner
Art Unit 3743

9/19/05


Heidi Bennett
Supervisor, Patent Examiner
Group 3700